



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply.

EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division



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10/19/99

MEMORANDUM

SUBJECT: Mevinphos: Residue Chemistry Chapter of the Reregistration Eligibility Decision Document. Chemical I.D. No. 015801. Case No. 0250. DP Barcode D259802.

FROM: William J. Hazel, Ph.D., Chemist
Reregistration Branch 1
Health Effects Division (7509C)

THRU: Whang Phang, Ph.D., Branch Senior Scientist
Reregistration Branch 1
Health Effects Division (7509C)

TO: Joseph Nevola/Robert McNally (PM 60)
Special Review and Reregistration Division (7508W)

Attached is the Residue Chemistry Chapter of the Reregistration Eligibility Decision (RED) document prepared by Reregistration Branch 1 of the Health Effects Division (HED). This review was written by Dynamac Corp., an EPA contractor, and has been revised to reflect current Agency policies. It has undergone secondary review by the Exposure Team of RRB1 and HED's Chemistry Science Advisory Council.

In order to prevent their revocation, AMVAC Chemical Corp. intends to support tolerances for mevinphos residues in or on several fruits and vegetables to permit importation of these commodities from Mexico into the U.S. All mevinphos-containing products have been cancelled in the U.S., i.e., mevinphos is no longer an active ingredient in any pesticide product registered in the U.S. The current registrant in Mexico is an American Cyanamid Co. (AMCY) subsidiary although AMVAC is reportedly planning to take over that registration. Note that mevinphos is reportedly also marketed in areas other than Mexico such as Europe, Australia, Thailand, and the Republic of South Africa (personal communication with Ian Chart of AMVAC, 7/23/99). Mevinphos appears also to be used in South America as most positive grape samples monitored by USDA's Pesticide Data Program originated in Chile. HED remains uncertain of the use directions to appear on Mexican labels. The current AMCY use directions do not agree with the parameters of the recent field trials conducted in

Mexico. AMVAC claims that the Mexican label will be amended to reflect the Mexican field trial parameters.

Note that the terms of an earlier agreement reached between AMVAC and the Agency have been summarized in the memorandum by G. Kramer (7/16/96, D223005 and D227401). It specified the number of Mexican field trials to be conducted, recently conducted U.S. trials, submission of Green Giant Co. monitoring data (over multiple seasons), need for grape and tomato processing studies, and agreement between U.S. and Mexican field trial use rates and PHIs. HED does not feel that the terms of this agreement have been met. As a result, additional magnitude of the residue data in plants are required.

These additional data are needed to permit mevinphos tolerance reassessment. The reasons for requiring these data are as follows: (i) tolerances may not be set higher than necessary, which may occur using the existing database; (ii) existing trials do not reflect current use patterns in Mexico and may not support revised Mexican labeling that is planned; (iii) monitoring data suggest that lower tolerances will likely be appropriate in many cases; (iv) monitoring data also demonstrate grape samples from Chile bearing detectable residues; (v) Green Giant Co. monitoring data from Mexico were never submitted; (vi) residue results, application rates, and the formulation tested in Mexico vs. those associated with the U.S. trials usually render the U.S. trials of little utility in supporting tolerance reassessment; and (vii) grape and tomato processing studies were never conducted. To permit mevinphos tolerance reassessment, one or more additional field trials have been required for all commodities except cucumbers and melons. These field trials are all to be conducted in Mexico with the exception of several grape trials also to be conducted in Chile, Argentina, and Europe. Tolerance reassessment cannot occur until these additional field trials have been completed, until supporting storage stability data have been submitted, until grape and tomato processing studies have been conducted, and until the revised use directions to officially appear on Mexican labels have been received by the Agency.

cc: W. Hazel (HED), C. Olinger (HED), F. Fort (HED), List A Reg. Std. File, RF
RRB1:CM2:722J:WHazel:305-7677:wjh:10/19/99
RDI: RRB1 ExpoTeam:10/6/99:ChemSAC:10/6/99:W.Phang:10/18/99

MEVINPHOS

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 015801; Case 0250

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MEVINPHOS

REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 015801; Case 0250

INTRODUCTION

Mevinphos [methyl 3-[(dimethoxyphosphinyl)oxy]butenoate] is a contact/systemic organophosphate insecticide that was previously registered in the United States by AMVAC Chemical Corporation under the trade name Phosdrin® for use on fruit and vegetable crops, cereal grains, and non-grass animal feed crops. There are presently no registered uses for mevinphos in the United States. However, AMVAC continues to support the use of mevinphos in Mexico as a broadcast foliar application to selected fruits and vegetables that can be imported to the U.S.

REGULATORY BACKGROUND

Mevinphos is a List A reregistration chemical and was the subject of a Registration Standard Chapter (11/25/87), which summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes.

Due to concerns over agricultural worker exposure and safety, EPA was prepared (6/30/94) to issue a Notice of Intent to Suspend all mevinphos registrations. Instead, AMVAC requested voluntarily cancellation of all its U.S. registrations for products containing mevinphos. The Agency granted this request effective 7/1/94 (59 *FR* 38973, 8/1/94); this cancellation order was later amended (60 *FR* 17357, 4/5/95) to extend the distribution, sale, and use of AMVAC's mevinphos-containing products until 11/30/95. As all registered uses of mevinphos in the U.S. were canceled, the Agency subsequently proposed revoking all mevinphos tolerances (60 *FR* 300393, 8/2/95). In its proposal, the Agency also noted that a preliminary acute dietary risk assessment based upon the available data indicated a concern for acute exposure to mevinphos, particularly for infants and children.

In response to this proposal, AMVAC requested (letter dated 10/31/95) that the Agency not revoke tolerances for mevinphos residues in/on selected fruits and vegetables as AMVAC was supporting the continued use of mevinphos in Mexico on commodities which are imported into the U.S. The uses being supported include the following crops: broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce (head and leaf),

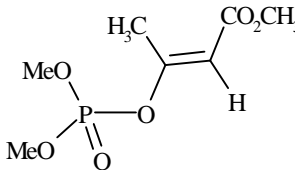
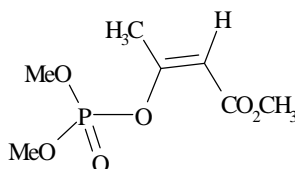
melons, peppers, peas (succulent), spinach, squash (summer), strawberries, and tomatoes. AMVAC also provided (letter dated 11/10/95) its own acute dietary exposure analysis for mevinphos residues based upon the crop uses they were continuing to support.

Several submissions of data have been received since the Registration Standard was issued. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of mevinphos.

Tolerances for residues of mevinphos in/on plant raw agricultural commodities (RACs) have been established under 40 CFR §180.157 and range from 0.2 ppm in/on citrus fruits, cucumbers and tomatoes to 2 ppm in/on watercress. A 4 ppm tolerance has also been established for residues in dehydrated parsley, which is the only processed commodity having a tolerance for mevinphos residues. No tolerances have been established for the mevinphos residues in animal commodities.

Mevinphos residues of concern in plants include the α - and β -isomers of mevinphos (DP Barcode D189713, S. Knizner, 7/29/93). Based upon the available animal metabolism data (DP Barcode D183036 and D189714, S. Knizner, 2/1/93 and 8/16/93), HED concluded that quantifiable residues of mevinphos are unlikely to occur in livestock [CFR 40 180.6(a)(3)]; therefore, tolerances in animal commodities are not required. The chemical names and structures of α - and β -mevinphos are depicted in Figure A.

Figure A. Chemical name and structure of mevinphos residues of concern in plants.

Common Name/Chemical Name	Chemical Structure
α-Mevinphos 2-carbomethoxy-1 methylvinyl dimethyl phosphate, cis isomer	
β-Mevinphos 2-carbomethoxy-1 methylvinyl dimethyl phosphate, trans isomer	

SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System (REFS) on 12/18/98 indicated that there are no mevinphos end-use products (EPs) registered for use on food/feed crops in the U.S. However, AMVAC Chemical Corporation is continuing to support the use of mevinphos on selected fruits and vegetables grown in Mexico (letter of 10/31/95), which may be imported into the U.S.

A translation of the American Cyanamid de Mexico (AMCY) mevinphos EP label with use directions for fruits and vegetables has been submitted by AMVAC; note that AMVAC intends to transfer this registration from AMCY to AMVAC. Also, a Spanish version of this label was made available. Neither of these versions agree with each other or with the parameters of the recently-conducted Mexican field trials. In order to adequately assess the available residue data and reassess tolerances, copies of revised labels for mevinphos EPs approved by the Mexican government must be submitted along with English translations.

In the interim, the Agency will assume that the residue field trials recently conducted in Mexico (DP Barcodes D196769 and D248311, W. Hazel, 10/19/99) reflect the maximum application rates (1x) and minimum preharvest intervals (PHI) allowed in Mexico for the crop uses being supported by AMVAC. These studies indicate that mevinphos (SC/L) is applied as a single broadcast application per crop season in Mexico at up to 440 g ai/ha (0.39 lb ai/A) on lettuce (leaf and head), spinach, celery, broccoli, cabbage, grapes and strawberries and at up to 220 g ai/ha (0.2 lb ai/A) on succulent peas, tomatoes, peppers, cucumbers, summer squash, and melons. The minimum PHI is 3 days for each crop with the exceptions of leaf lettuce (10 days), spinach (7 days), celery (5 days), and grapes (5 days). The current Mexican label permits foliar applications as often as needed at rates up to 480 g ai/ha with 1- or 2-day PHIs, obviously quite different from the field trial parameters.

A tabular summary of the residue chemistry science assessments for reregistration of mevinphos is presented in Table A. The conclusions listed in Table A regarding the reregistration eligibility of mevinphos uses are based on the presumed use pattern of mevinphos in Mexico.

OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on acceptable lettuce, strawberry, and turnip metabolism studies (D183034 and D184563, S. Knizner, 2/8/93; and D189713, S. Knizner, 7/27/93). The residues of concern in plants include the α - and β -isomers of mevinphos. Although cis-mevinphos acid was also found in all samples, it was present at lower levels than α - and β -mevinphos

whenever all of these compounds were found in the same matrix. Additionally, though cis-mevinphos acid was the only residue identified in turnip roots, it represented less than 6% of the total radioactive residues (TRR).

In the lettuce metabolism study, TRR were 6.29 ppm in/on lettuce harvested 5 days following the last of three foliar applications of [^{14}C]mevinphos each at 0.85 lb ai/A. The principal component of the TRR was identified as R/S hydroxybutyrate methyl ester (55.4% TRR, 3.48 ppm). β -Mevinphos accounted for 9.8% TRR (0.62 ppm), α -mevinphos 6.4% TRR (0.40 ppm), and cis mevinphos acid 1.8% TRR (0.12 ppm). Acetoacetic acid and/or DL-3-hydroxybutyric acid comprised 12.7% TRR (0.80 ppm) and methyl acetoacetic acid accounted for 3.8% TRR (0.24 ppm).

In the strawberry metabolism study, TRR were 2.17 ppm in/on strawberries harvested 2 days following the last of three foliar applications of [^{14}C]mevinphos each at 0.85 lb ai/A. The largest component of the ^{14}C -residues was identified as R/S hydroxybutyrate methyl ester (35.8% TRR, 7.01 ppm) followed by α -mevinphos (21.7% TRR, 4.24 ppm). Other compounds identified included acetoacetic acid and/or DL-3-hydroxybutyric acid (12.9% TRR 2.52 ppm), methyl acetoacetate at 9.3% TRR (1.83 ppm), β -mevinphos at 7.6% TRR (1.49 ppm) and cis-mevinphos acid at 2.3% TRR (0.44 ppm).

In the turnip metabolism study, TRR were 5.80 and 0.39 ppm in/on turnip tops and roots harvested 3 days following the last of three foliar applications each at 0.43 lb ai/A. In tops, the largest component of the TRR was identified as R/S-3-hydroxybutyrate methyl ester at 42.8% TRR (2.48 ppm), followed by DL-3-Hydroxybutyric acid and/or acetoacetic acid at 6.1% TRR (0.36 ppm) and cis-mevinphos acid at 5.6% TRR (0.32 ppm). β -Mevinphos accounted for 4.2% TRR (0.24 ppm) and α -mevinphos 4.0% TRR (0.23 ppm). In roots, cis-mevinphos acid accounted for 6.3% TRR (0.02 ppm), and seven unknown polar components together accounted for 63.3% TRR (0.25 ppm). Neither isomer of mevinphos was detected in turnip roots.

OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of mevinphos residues in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies (D183036, S. Knizner, 2/1/93; and D189714, S. Knizner, 8/11/93). HED has concluded that residues of mevinphos in animal commodities represent a Category 3 situation [40 CFR §180.6(a)(3)], in that there is no reasonable expectation of residues in meat, milk, poultry or eggs. In the ruminant metabolism study, dairy goats were dosed with [^{14}C]mevinphos at an average of either 2.9 or 18 ppm for 5 consecutive days. TRR levels were dose dependent and were highest in liver and kidney and lowest in muscle. [^{14}C]Mevinphos was extensively metabolized and incorporated into endogenous biomolecules, such as fatty acids, cholesterol, amino acids, and lactose. Mevinphos

per se was not detected in tissues or milk. In ruminants, there is no reasonable expectation of mevinphos residues transferring from feed items to livestock commodities. Therefore, tolerances for mevinphos in ruminant commodities are not required.

In the poultry metabolism study, two groups of laying hens were dosed with [^{14}C]mevinphos at 2.3 or 23 ppm for 3 consecutive days. For high dose hens, TRR levels ranged from ~1.9 ppm in liver and kidney to 0.2 ppm in muscle; TRR in eggs by Day 3 were 1.27 ppm. [^{14}C]Mevinphos was extensively metabolized and incorporated into endogenous biomolecules in hens. Mevinphos and its O-desmethyl metabolite were not detected in any tissues or eggs. In poultry, there is no reasonable expectation of mevinphos residues transferring from feed items to livestock commodities. Therefore, tolerances for mevinphos in poultry commodities are not required.

OPPTS GLN 860.1340: Residue Analytical Methods

The Pesticide Analytical Manual (PAM) Vol. II lists a cholinesterase-inhibition spectrophotometric method (Method I) for determining residues of mevinphos in/on plant commodities. As this method is not specific for mevinphos residues, the Registration Standard (11/87) recommended that an existing GC/FPD method, which separately quantifies α - and β -mevinphos, be used for tolerance enforcement. In this GC method, mevinphos residues are extracted into ethyl acetate, concentrated to an aqueous solution, acidified, partitioned into methylene chloride, and determined by GC.

A similar GC/FPD (phosphorus mode) method has been validated using ^{14}C -labeled samples from the lettuce metabolism study and using fortified control samples of numerous plant commodities. For this method, mevinphos residues are extracted with acetonitrile and filtered. Sodium chloride is added to the extract and the resulting aqueous phase is discarded. Residues in the resulting acetonitrile phase are then dried over anhydrous Na_2SO_4 , concentrated, and redissolved in acetone. Residues of α - and β -mevinphos are then determined by GC/FPD (phosphorus mode). The reported limit of quantitation (LOQ) for mevinphos (α + β -isomers) is typically 0.02 ppm. However, the method has only been validated down to an LOQ of 0.05 ppm using fortified control samples analyzed in conjunction with field residue data.

In all of the recent field trials (1993-1997), the adequate GC/FPD (phosphorus mode) method discussed above was used for collecting data on both α - and β -mevinphos in plant commodities. Prior to validation of this GC/FPD method by the Agency, an independent laboratory validation of this method must be conducted in accordance with PR Notice 96-1 if the registrant chooses this method as a tolerance enforcement

method. Alternatively, FDA Multiresidue Protocol A or D would be sufficient (see below).

As tolerances are not required for mevinphos residues in animal commodities, methodology for determining mevinphos in animal tissues is also not required.

OPPTS GLN 860.1360: Multiresidue Method Testing

The Registration Standard (11/87) indicated that α - and β -mevinphos are completely recovered using FDA Multiresidue Protocols A and D (PAM I Sections 242.2 and 232.4), but are not recovered using Protocol E (PAM I Sections 211.1 and 212.1).

OPPTS GLN 860.1380: Storage Stability Data

The Mevinphos Registration Standard (11/87) cited storage stability data indicating that residues of mevinphos are stable at -20 C in broccoli for up to 146 days and stable at 5 C for up to 43 days in cauliflower, 32 days in beet tops, 21 days in tomatoes, and 50 days in citrus fruits. Adequate data have also been submitted indicating that mevinphos is stable in Brassica vegetables at -20 C for up to 63 days and in frozen lettuce for up to 61 days.

In recent residue studies on grapes, squash, and pea vines and hay, sample analyses were completed within ~1 month of collection; therefore, supporting storage stability data are not required to support these field trials. In addition, the available storage stability data adequately support the broccoli, cabbage, celery, lettuce, and spinach field trial data. However, additional storage stability data are required to support the residue data on pea pods, tomatoes, peppers, cucumbers, melons, and strawberries.

Data are required depicting the storage stability of mevinphos residues in frozen (<0 C) tomatoes for up to 2 months, melons for up to 3 months, succulent pea pods and peppers for up to 4 months, strawberries for up to 5 months, and cucumbers for up to 6 months.

Additional residue field trials are being required to support import tolerances; if samples from these studies are stored for more than one month prior to analysis, concurrent supporting storage stability studies should be conducted using representative commodities.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

Provided adequate label directions are submitted for mevinphos EPs registered for use in Mexico and provided deficiencies pertaining to storage stability of residues in these crops are resolved, adequate mevinphos residue data are available for cucumbers and melons (crop subgroup 9-A). For each of these crops, an adequate number of field trials has been conducted depicting mevinphos residues resulting from the application of mevinphos at the proposed maximum use rate in Mexico or regions in the U.S. representative of Mexico.

Additional residue data are required reflecting the use of mevinphos in Mexico at the maximum proposed use rate in order to support import tolerances for the following crops: broccoli, cabbage, cauliflower, celery, grapes, leaf and head lettuce, succulent peas, peppers, summer squash, spinach, strawberries, and tomatoes. Based on the available Mexican field trial data, an additional two residue field trials are required on broccoli, cabbage, celery, leaf lettuce, succulent peas, peppers, summer squash, spinach, and strawberries. Three and four additional field trials are required on head lettuce and tomatoes, respectively. For each crop except grapes, the required field trials should be conducted in Mexico at separate locations using representative mevinphos formulations at the maximum proposed use rate. In the case of grapes, an additional three trials must be conducted in Chile, two in Italy, and one each in France and Argentina. Trials outside of Mexico are particularly important for grapes because most PDP grape monitoring samples bearing detectable residues of mevinphos originated in Chile.

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities of grapes and tomatoes are not fulfilled. Processing studies on grapes and tomatoes are required to support import tolerances for these crops if the imported crops are likely to be processed in the U.S. or if their processed commodities are imported from Mexico. Alternatively, the registrant may provide information/data indicating that mevinphos treated grapes and tomatoes are unlikely to be used for processing in Mexico or processed in the U.S. once imported

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs are fulfilled. In the reviews of the ruminant and poultry metabolism studies (DP Barcodes D183036 and D189714, S. Knizner, 2/1/93 and 8/16/93), HED previously concluded that there is no reasonable expectation of residues occurring in animal commodities [40 CFR 180.6(a)(3)] and recommended granting waivers for the requirements for livestock feeding studies. In addition, no significant animal feed items are associated with any of the crops for which import tolerances are being supported.

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, Irrigated Crops

As mevinphos is not registered for use on potable water or aquatic crops, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1460: Magnitude of the Residue in Food-handling Establishments

Mevinphos is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLNs 860.1850 and 860.1900: Confined and Field Accumulation in Rotational Crops

Residue chemistry data are not required under these guideline topics as mevinphos is being supported only for use in Mexico on selected fruits and vegetables imported into the U.S.

Table A. Residue Chemistry Science Assessments for Reregistration of Mevinphos.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1200: Directions for Use	N/A	Yes ²	
860.1300: Plant Metabolism	N/A	No	42475601 ³ 42540101 ³ 42674001 ⁴
860.1300: Animal Metabolism	N/A	No	42476701 ⁵ 42659201 ⁶
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	Yes ⁷	00036989 00036990 00089559 00113334 00147425 42964601 ⁸
- Animal commodities	N/A	No	
860.1360: Multiresidue Methods	N/A	No	
860.1380: Storage Stability Data	N/A	Yes ⁹	00113309 00147425 41546501 ¹⁰ 44595218 ⁸ 44595221 ⁸
860.1500: Crop Field Trials			
<u>Leafy Vegetables (except <i>Brassica</i> Vegetables) Group</u>			
- Celery	1.0 [§180.157]	Yes ¹¹	44595203 ⁸ 44595214 ⁸
- Lettuce	0.5 [§180.157]	Yes ¹²	44595204 ⁸ 44595221 ⁸ 44608502 ⁸
- Spinach	1.0 [§180.157]	Yes ¹³	44595207 ⁸ 44595217 ⁸
<u>Brassica Leafy Vegetables Group</u>			
- Broccoli	1.0 [§180.157]	Yes ¹⁴	44595201 ⁸ 44608501 ⁸
- Cabbage	1.0 [§180.157]	Yes ¹⁵	44595202 ⁸ 44595218 ⁸
<u>Legume Vegetables Group</u>			
- Peas	0.25 [§180.157]	Yes ¹⁶	44595206 ⁸ 44595215 ⁸
<u>Fruiting Vegetables (except Cucurbits) Group</u>			
- Peppers	0.25 [§180.157]	Yes ¹⁷	44595210 ⁸
- Tomatoes	0.2 [§180.157]	Yes ¹⁸	44595211 ⁸

Table A. (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
Cucurbit Vegetables Group			
- Cucumbers	0.2 [§180.157]	No ¹⁹	44595213 ⁸
- Melons	0.5 [§180.157]	No ¹⁹	44595205 ⁸ 44595220 ⁸
- Squash, summer	0.25 [§180.157]	Yes ²⁰	44595209 ⁸
Miscellaneous Commodities			
- Grapes	0.5 [§180.157]	Yes ²¹	44595212 ⁸ 44595219 ⁸
- Strawberries	1.0 [§180.157]	Yes ²²	44595208 ⁸ 44595216 ⁸
860.1520: Processed Food/Feed			
- Grapes	None	Yes ²³	
- Tomatoes	None	Yes ²³	
860.1480: Meat, Milk, Poultry, and Eggs	None	No	
860.1400: Water, Fish, and Irrigated Crops	None	NA	
860.1460: Food Handling	None	NA	
860.1850: Confined Rotational Crops	N/A	NA	
860.1900: Field Rotational Crops	None	NA	

1. Only references pertaining to the import tolerances being supported by AMVAC Chemical Corp. are included in this table. References were reviewed in the Mevinphos Registration Standard dated 11/25/87, unless otherwise noted.
2. Mevinphos EP labels with use directions for fruits and vegetables in Mexico have not been submitted. In order to adequately assess the available residue data, copies of labels for mevinphos EPs used in Mexico must be submitted along with translations.
3. DP Barcodes D183034 and D184563, S. Knizner, 2/9/93.
4. DP Barcode D189713, S. Knizner, 7/29/93.
5. DP Barcode D183036, S. Knizner, 2/1/93.

Table A (continued).

6. DP Barcode D189714, S. Knizner, 8/16/93.
7. The proposed GC/FPD (phosphorus mode) tolerance enforcement method must undergo an independent laboratory validation prior to being validated by the Agency (DP Barcodes D196769 and D248311, W. Hazel, 10/19/99). Alternatively, FDA Multiresidue Protocol A or D has been demonstrated to be adequate for tolerance enforcement.
8. DP Barcodes D196769 and D248311, W. Hazel, 10/19/99.
9. To support the existing residues data on cucumbers, melons, pea pods, peppers, strawberries and tomatoes, data are required depicting the storage stability of mevinphos residues in frozen (<0 C) tomatoes for up to 2 months, melons for up to 3 months, succulent pea pods and peppers for up to 4 months, strawberries for up to 5 months, and cucumbers for up to 6 months. Additional residue field trials are being required to support import tolerances; if samples from these studies are stored for more than one month prior to analysis, concurrent supporting storage stability studies should be conducted using representative commodities.
10. DEB No. 6848, C. Olinger, 8/2/90.
11. Two additional field trials are required in Mexico depicting mevinphos residues in/on untrimmed celery harvested 5 days following a single broadcast foliar application of mevinphos at the proposed maximum use rate of 440 g ai/ha. The two tests should be conducted at separate locations and a minimum of two composited samples should be collected from each test for analysis.
12. Additional field trials are required in Mexico depicting mevinphos residues in/on leaf lettuce and head lettuce (untrimmed) harvested following a single broadcast foliar application of mevinphos at the proposed maximum use rate of 440 g ai/ha. The proposed PHIs for leaf and head lettuce are 10 and 3 days, respectively. Two additional tests are required for leaf lettuce and three tests are required on head lettuce. For each crop, the tests should be conducted at separate locations and a minimum of two composited samples should be collected from each test for analysis.
13. Two additional field trials are required in Mexico depicting mevinphos residues in/on spinach harvested 7 days following a single broadcast foliar application of mevinphos at the proposed maximum use rate of 440 g ai/ha. The two tests should be conducted at separate locations and a minimum of two composited samples should be collected from each test for analysis.
14. Two additional field trials are required in Mexico depicting mevinphos residues in/on broccoli harvested 3 days following a single broadcast foliar application of mevinphos at the proposed maximum use rate of 440 g ai/ha. The two tests should be conducted at separate locations and a minimum of two composited samples should be collected from each test for analysis.
15. Two additional field trials are required in Mexico depicting mevinphos residues in/on cabbage (untrimmed) harvested 3 days following a single broadcast foliar application of mevinphos at the proposed maximum use rate of 440 g ai/ha. The two tests should be conducted at separate locations and a minimum of two composited samples should be collected from each test for analysis.

Table A (continued).

16. Two additional field trials are required in Mexico depicting mevinphos residues in/on succulent peas harvested 3 days following a single broadcast foliar application of mevinphos at the proposed maximum use rate of 220 g ai/ha. The two tests should be conducted at separate locations and a minimum of two composited samples should be collected from each test for analysis. Residue data on vines and hay of succulent peas are not required as these commodities are not regulated livestock feed items.
17. Two additional field trials are required in Mexico depicting mevinphos residues in/on peppers 3 days following a single broadcast foliar application of mevinphos at the proposed maximum use rate of 220 g ai/ha. The two tests should be conducted at separate locations and a minimum of two composited samples should be collected from each test for analysis.
18. Four additional field trials are required in Mexico depicting mevinphos residues in/on tomatoes harvested 3 days following a single broadcast foliar application of mevinphos at the proposed maximum use rate of 220 g ai/ha. The two tests should be conducted at separate locations and a minimum of two composited samples should be collected from each test for analysis.
19. Adequate mevinphos residue data are also available for cucumbers and melons (crop subgroup 9-A) provided deficiencies pertaining to storage stability of residues in these crops are resolved.
20. Two additional field trials are required in Mexico depicting mevinphos residues in/on summer squash harvested 3 days following a single broadcast foliar application of mevinphos at the proposed maximum use rate of 220 g ai/ha. The two tests should be conducted at separate locations and a minimum of two composited samples should be collected from each test for analysis.
21. Three additional field trials are required to be conducted in Chile, two in Italy, and one each in France and Argentina in major grape-growing regions according to the labels in the test country. Adequate label directions must be submitted for mevinphos EPs registered for use in Mexico and countries in which the additional field trials are conducted..
22. Two additional field trials are required in Mexico depicting mevinphos residues in/on strawberries harvested 3 days following a single broadcast foliar application of mevinphos at the proposed maximum use rate of 440 g ai/ha. The two tests should be conducted at separate locations and a minimum of two composited samples should be collected from each test for analysis.
23. Processing studies on grapes and tomatoes are required to support import tolerances for these crops if the imported crops are likely to be processed in the U.S. or if their processed commodities are imported from Mexico. Alternatively, the registrant may provide information/data indicating that mevinphos treated grapes and tomatoes are unlikely to be used for processing in either Mexico or the U.S.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for mevinphos residues are currently expressed in terms of the combined residues of the α - and β -isomers of mevinphos [40 CFR §180.157], which are the residues of concern in plants. A summary of the mevinphos tolerance reassessment and recommended modifications in commodity definitions are presented in Table B.

Tolerances Listed Under 40 CFR §180.157:

Provided acceptable mevinphos labels are submitted and deficiencies pertaining to storage stability of residues are resolved, sufficient data are available to reassess tolerances for mevinphos in/on cucumbers and melons imported from Mexico. Additional residue data are required for broccoli, cabbage, cauliflower, celery, grapes, lettuce, peas, peppers, spinach, summer squash, strawberries, and tomatoes before the existing tolerances can be reassessed.

Although additional storage stability data are required to support the cucumber and melon field trial data, the available data indicate the established tolerances could be lowered to 0.05 ppm for cucumbers and 0.1 ppm for melons if the revised Mexican label directions agree with the field trial parameters and if the existing cucumber residue data are validated by storage stability data.

AMVAC is only supporting import tolerances for mevinphos residues in/on the following commodities: broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce (leaf and head), melons, peas (succulent), peppers, summer squash, spinach, strawberries, and tomatoes. Tolerances for all other crops/commodities should be revoked.

Tolerances Needed Under 40 CFR §180.157:

Tolerances may be needed for mevinphos residues in/on grape and tomato processed commodities. However, before the need for mevinphos tolerances can be assessed, residue data are required depicting mevinphos residues in grape and tomato processed commodities.

Table B. Tolerance Reassessment Summary for Mevinphos.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Tolerances listed under 40 CFR §180.157:			
Alfalfa	1.0	Revoke	Uses on these crops/commodities are not being supported.
Apples	0.5		
Artichokes	1.0		
Beans	0.25		
Beets, garden (inc. tops)	1.0		
Broccoli	1.0	TBD ^a	Additional residue data are required.
Brussels sprouts	1.0	Revoke	Use on this crop is not being supported.
Cabbage	1.0	TBD	Additional residue data are required.
Carrots	0.25	Revoke	Uses on this crop/commodity is not being supported.
Cauliflower	1.0	TBD	Additional residue data are required.
Celery	1.0	TBD	Additional residue data are required.
Cherries	1.0	Revoke	Uses on these crops/commodities are not being supported.
Chicory, red (tops) (radicchio)	0.5		
Citrus	0.2		
Clover	1.0		
Collards	1.0		
Corn, field, forage	1.0		
Corn, field, grain	0.25		
Corn, pop, forage	1.0		
Corn, pop, grain	0.25		
Corn, sweet, (K+CWHR)	0.25	Revoke	Uses on this crop is not being supported.
Corn, sweet, forage	1.0		
Cucumber	0.2	0.05	Import tolerance based upon Mexican field trial data.
Eggplant	0.25	Revoke	Uses on this crop is not being supported.
Grape	0.5	TBD	Additional residue data are required.
Kale	1.0	Revoke	Uses on this crop is not being supported.
Lettuce	0.5	TBD	Additional residue data are required.
Melon	0.5	0.1	Import tolerance based upon Mexican and U.S. field trial data. <i>melon (Crop subgroup 9-A)</i>

Table B. Continued.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Mustard greens	1.0	Revoke	Uses on these crops/commodities are not being supported.
Okra	0.25		
Onions, green	0.25		
Parsley	1.0		
Parsley, dehydrated	4.0		
Peaches	1.0		
Pears	0.5		
Peas	0.25	TBD	<i>Pea, succulent</i> Additional residue data are required.
Peas, vines	1.0	Revoke	No longer considered a regulated livestock feed item.
Pepper	0.25	TBD	Additional residue data are required.
Plums	1.0	Revoke	Uses on these crops/commodities are not being supported.
Potatoes	0.25		
Raspberries	1.0	Revoke	Uses on these crops/commodities are not being supported.
Sorghum, forage	1.0		
Sorghum, grain	1.0		
Spinach	1.0	TBD	Additional residue data are required.
Squash, summer	0.25	TBD	
Strawberry	1.0	TBD	
Tomato	0.2	TBD	
Trefoil, birdsfoot, forage	1.0	Revoke	Uses on these crops/commodities are not being supported
Trefoil, birdsfoot, hay	1.0		
Turnips	0.25		
Turnips, tops	1.0		
Walnuts, meats (shells removed)	0.25		
Watercress	2.0		
Watermelons	0.5		Covered by melons (Crop subgroup 9-A)
Tolerances needed under 40 CFR §180.157:			
Grape, juice	None	TBD	Data depicting residues in grape processed fraction are required.
Grape, raisin			
Tomato, paste	None	TBD	Data depicting residues in tomato processed fraction are required
Tomato, puree			

^a TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.

DIETARY EXPOSURE ASSESSMENT SUMMARY

For reregistration and risk assessment purposes, adequate plant and animal metabolism data are available. However, acceptable residue data are tentatively available only for imported cucumbers and melons. Additional residues data are required to reassess import tolerances for broccoli, cabbage, cauliflower, celery, lettuce, peas, peppers, spinach, squash, strawberries and tomatoes. In addition, no residue data are available for grape and tomato processed commodities. For exposure refinement purposes, PDP and FDA monitoring data are available for the calculation of anticipated residues. Also, percent crop imported and percent crop treated data are available from the Biological and Economic Analysis Division.

CODEX HARMONIZATION

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for mevinphos in/on various fruit and vegetable commodities (see *Guide to Codex Maximum Limits For Pesticide Residues*) ranging from 0.05 to 1 mg/kg. However, the Joint Meeting on Pesticide Residues (JMPR, 1997) recommended the withdrawal of all mevinphos MRLs with the exceptions of MRLs for cabbage, common bean, and leeks. Codex MRLs for mevinphos are currently expressed as the sum of cis- and trans-mevinphos for plant commodities, as are the U.S. tolerances. A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in Table C.

As MRLs for all commodities except cabbage, common beans, and leeks have been recommended for withdrawal, there would be no question of compatibility between Codex MRLs and U.S. import tolerances for any crop/commodity except cabbage. Additional field trial data are required to support the U.S. import tolerance for cabbage; however, the available Mexican field trial data indicate that a tolerance of 0.05 ppm could be acceptable for mevinphos residues in/on cabbage. If the additional residues data support a 0.05 ppm tolerance, then the U.S. import tolerance would be equivalent to the proposed 0.05 mg/kg MRL (Step 3a) for cabbage.

Table C. Codex MRLs for mevinphos and applicable U.S. tolerances.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined)	MRL (mg/kg)	Step ^a		
Apple	0.5	CXL	None	
Apricot	0.2	CXL	None	
Broccoli	1	CXL	TBD	Additional data are required.
Brussels sprouts	1	CXL	None	
Cabbages, Head	1	CXL	TBD	Additional field trial data are required, but the available data support a 0.05 ppm tolerance.
Cabbages, Head	0.05	3(a)		
Carrot	0.1	CXL	None	
Cauliflower	1	CXL	TBD	Additional data are required.
Cherries	1	CXL	None	
Citrus fruits	0.2	CXL	None	
Common bean (pods and/or immature seeds)	0.1	CXL	None	
Common bean (pods and/or immature seeds)	0.05	3(a)		
Cucumber	0.2	CXL	0.05	Residue data support a lower tolerance.
Grapes	0.5	CXL	TBD	Additional data are required.
Kale	1	CXL	None	
Leeks	0.02 (*) ^b	3	None	
Lettuce, Head	0.5	CXL	TBD	Additional data are required.
Melons, except Watermelon	0.05	CXL	0.1	Residues data support a higher tolerance; includes watermelon.
Onion, Bulb	0.1	CXL	None	
Peach	0.5	CXL	None	
Pear	0.2	CXL	None	
Peas	0.1	CXL	TBD	Additional data are required.
Potato	0.1	CXL	None	
Spinach	0.5	CXL	TBD	Additional data are required.
Strawberry	1	CXL	TBD	
Tomato	0.2	CXL	TBD	
Turnip, Garden	0.1	CXL	None	

^a With the exceptions of MRLs for cabbage, common bean, and leeks, MRLs for mevinphos have been recommended for withdrawal (1997 JMPR).

^b Asterisk designates MRL set at the limit of quantitation.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

DEB No. : 6848
Subject: Over-Tolerance Residues of Mevinphos on Lettuce, 6(a) (2) Data.
From: C. Olinger
To: J. Miller/D. Peacock
Date: 8/2/90
MRID(s): 41546501 and 41546502

DP Barcode: D183036
Subject: Mevinphos. Guideline 171-4(b) Nature of the Residue in Lactating Goats.
From: S. Knizner
To: K. Samek
Date: 2/1/93
MRID(s): 42476701

DP Barcode: D183034 and D184563
Subject: Mevinphos. Guideline 171-4(a) Nature of the Residue in Lettuce and Strawberries.
From: S. Knizner
To: K. Samek
Date: 2/9/93
MRID(s): 42475601 and 42540101

DP Barcode: D189713
Subject: Mevinphos. Guideline 171-4(a) Nature of the Residue in Turnips.
From: S. Knizner
To: K. Samek
Date: 7/29/93
MRID(s): 42674001

DP Barcode: D189714
Subject: Mevinphos. Guideline 171-4(b) Nature of the Residue in Poultry.
From: S. Knizner
To: K. Samek
Date: 8/16/93
MRID(s): 42659201

DP Barcodes: D223005 and D227401
Subject: Mevinphos- Field Trial Data Requirements for Establishing Tolerances on Imported Commodities.
From: G.F. Kramer

To: D. McCall
Date: 7/17/96
MRID(s): None

DP Barcodes: D196769 and D248311

Subject: Radiolabeled Method Validation Data for Proposed Enforcement Method and
Magnitude of the Residue Data Supporting Import Tolerances for Mevinphos.

From: W. Hazel

To: J. Nevola

Dated: 10/19/99

MRID(s): 42964601, 44595201-44595221, 44608501, and 44608502.

RESIDUE CHEMISTRY CITATIONS

The following MRID citations provided information pertaining to mevinphos import tolerances on selected fruits and vegetables.

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00036990 Casida, J.E. (19??) Enzymatic Determination of OS 2046 in Agricultural Crops: Enzyme Inhibition--delta pH Method. (Unpublished study received Jun 5, 1956 under PP0078; prepared by Univ. of Wisconsin, submitted by Shell Chemical Co., Washington, D.C.; CDL:092358-E)

00089559 Shell Chemical Corporation (1957) Determination of Anticholinesterase in Plant and Animal Tissues. Method dated Mar 1957. (Unpublished study received Apr 15, 1957 under PP0123; CDL:090154-Z)

00113309 Shell Chemical Corp. (1958) [Phosdrin: Residues in Oranges and Other Crops]. (Compilation; unpublished study received on unknown date under PP0200; CDL:098743-A)

00113334 Shell Development Co. (1964) Determination of Phosdrin Insecticide in Crops and Animal Products: Analytical Method MMS-6/64. (Unpublished study received Jul 1, 1964 under unknown admin. no.; CDL:129696-A)

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- 42659201 Craine, E. (1993) A Residue Chemistry Study in the Laying Hen with (carbon 14)-Mevinphos: Lab Project Number: WIL-188001. Unpublished study prepared by WIL Research Labs., Inc. 320 p.
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- 42964601 Schweitzer, M.; Andrews, K. (1993) Enforcement Validation for the Determination of Mevinphos Residues in Crop Samples: Lab Project Number: SC930248. Unpublished study prepared by Battelle. 36 p.
- 44595201 Taylor, A.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Broccoli Grown in Mexico: Lab Project Number: AMV96001. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 69 p.{OPPTS 860.1500}
- 44595202 Kent, Y; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Cabbage Grown in Mexico: Lab Project Number: AMV96002. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 68 p.{OPPTS 860.1500}
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